

DOCKET NO.: AM100212 CON/WYNC-0331
Application No.: 10/661,182
Office Action Dated: September 20, 2004

PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

REMARKS

Claims 19 to 33 are pending in this application. Claims 19 to 33 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. The remaining rejections of the claims have been withdrawn. Applicants are amending claim 19.

Amendments to Claims

Applicants are herein amending claim 19, without prejudice or disclaimer, to specify that the conditions for which the methods of the invention are useful in treating specifically include obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation. No new matter is introduced by the amendment to claim 19. Support for the amendment may be found in the specification, *inter alia*, on page 10, lines 31-33. Applicants explicitly reserve the right to file one or more continuing applications directed to the cancelled subject matter.

Rejection under 35 U.S.C. § 112, First Paragraph

In the Office Action, claims 19 to 33 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly being non-enabled, specifically with respect to methods of treating eating disorders and sexual dysfunction. Applicants respectfully traverse the rejection because the specification enables a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and to use the invention commensurate in scope with claims 19 to 33. In an effort to expedite prosecution of the application, applicants are herein amending claim 19 to specify the method is useful in treatment of the following conditions: obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation. Applicants, however, are not conceding that the claim 19, as originally presented, was not fully enabled.

In order to establish a *prima facie* case of non-enablement, the following must be established by the Patent Office:

1. a rational basis as to
 - a. why the disclosure does not teach; or
 - b. why to doubt the objective truth of the statements in the disclosure that purport to teach;
2. the manner and process of making and using the invention
3. that correspond in scope to the claimed invention
4. to one of ordinary skill in the pertinent technology,
5. without undue experimentation, and
6. dealing with subject matter that would not already be known to the skilled person as of the filing date of the application.

Any rejection under 35 U.S.C. § 112, second paragraph, for lack of enablement, must include evidence supporting each of these elements. Applicants respectfully submit that the Office has failed to meet its burden of establishing a *prima facie* case of non-enablement.

It has been consistently held that the first paragraph of 35 U.S.C. § 112 requires nothing more than *objective* enablement. Furthermore, a specification that teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the first paragraph of 35 U.S.C. § 112, *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Stahelin v. Secher*, 24 U.S.P.Q.2d 1513, 1516 (B.P.A.I. 1992) (citing *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (C.C.P.A. 1971)). “[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to ... back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.” *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). In the instant application, no evidence has been provided of why the disclosure is insufficient or why the Office does not believe the statements contained therein. Accordingly, applicants respectfully submit that the Office has not met its burden.

It appears that the Office is challenging the objective truth of the use of the compounds to treat the various conditions, and, in particular, the nexus between 5-HT_{1A} receptor ligands and the treatment of obesity, eating disorders, vasomotor flushing, cocaine

addiction, alcohol addiction, and sexual dysfunction. Applicants have provided procedures for the assay to determine the affinity for the 5-HT transporter, the assay for the 5-HT_{1A} receptor, and the assay for the antagonist activity at 5-HT_{1A} receptor of the compounds useful in the methods of the invention in the specification on page 9, line 19 to page 10, line 11. Applicants have also provided data on page 10, lines 13 to 24 to show that representative compounds of the invention are combined serotonin reuptake inhibitors (SSRI) and 5-HT_{1A} antagonists. As such, they are useful for the treatment of diseases commonly treated with the *administration of SSRI antidepressants*, including obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation.

The nexus between SSRI antidepressants and the treatment of obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation is specifically recognized in the art. See, for example, US-B-6,169,098 [showing 5-HT_{1A} receptor antagonists are useful in the treatment of eating disorders (obesity, anorexia, bulimia), sexual disturbances, alcoholism, and thermoregulatory disorders (column 4, lines 24 to 32)]; Lee, *et al.*, *Formulary* 2002; 37: 312-319 (showing use of SSRIs in treatment of alcohol dependence; anorexia nervosa; bulimia nervosa; and premature ejaculation]; Stone, *et al.*, *Am. Fam. Physician* 2003; 68: 498-504 (describing use in the treatment of premature ejaculation); WO 00/34263 (describing use antagonist of 5HT_{1A} receptor, *inter alia*, in the treatment of alcohol abuse). Each of these documents was enclosed with the response to the previous Office Action.

Applicants disagree with the assertion that the Lee reference concludes that bulimia nervosa is the only eating disorder that may be treated with an SSRI. The reference also describes that, with respect to anorexia nervosa, “more recent studies have shown SSRIs to be quite effective, particularly if administered after weight restoration has occurred.” See page 317, first column. Applicants have herein amended claim 19 to specifically name anorexia nervosa and bulimia nervosa as conditions that may be treated in accordance with the method of the invention.

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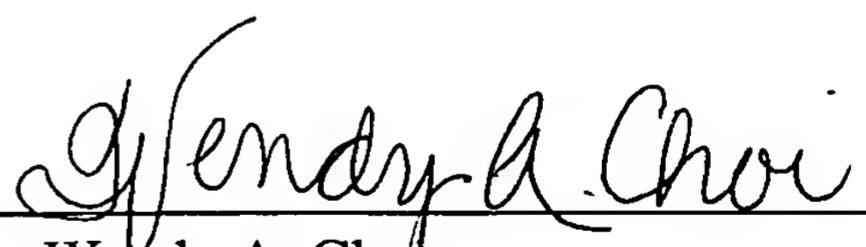
A lack of working examples with respect to methods of treating obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation does not automatically make a patent non-enabling. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Additionally, 35 U.S.C. § 112 does not demand a "working example," and an application cannot be fatally defective merely because it lacks one. *In re Long*, 151 U.S.P.Q. 640 (C.C.P.A. 1966); *In re Honn et al.*, 150 U.S.P.Q. 652 (C.C.P.A. 1966); *In re Bartholome et al.*, 156 U.S.P.Q. 20 (C.C.P.A. 1967); and *Ex parte Kenega*, 189 U.S.P.Q. 62 (Pat. Off. Bd. App. 1974).

Because there is a nexus between compounds having serotonin reuptake inhibitory (SSRI) and 5-HT_{1A} antagonist activity and methods of treating obesity, anorexia nervosa, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation set forth in claims 19 to 33 (as herein amended), applicants respectfully submit that there is not a reasonable basis for rejecting the claims. Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

Conclusions

Applicants respectfully request reconsideration and withdrawal of the rejection of the claims in view of the remarks. If the Examiner has any questions, the Examiner is invited to call the undersigned at (215) 557-3861.

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